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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/481,572	01/11/2000	JACQUELINE J. SHAN	P8061-9013	5800

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/481,572

Applicant(s)

SHAN ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/13/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,10,23,26 and 28-44 is/are pending in the application.
- 4a) Of the above claim(s) 26,28,29 and 31-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 10, 23, 30, 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The previous office action is vacated the following office action replaces it.

Election/Restrictions

The restriction requirement of record is vacated. The election of species is maintained. Applicant's election of the species, ischemic condition is noted. Since no prior art was found on ischemic condition the search is drawn to another species, namely, arrhythmia. Thus, claims 26, 28, 29, 31-38 are withdrawn from further consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 23, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23 it is not clear what a "methanol of ethanol extract" is ? It is a methanol or ethanol extract ?

In claim 44 it is not clear where the subject is in that claim. To whom is the extract being administered to ?

Claim 1 is rejected because claim 23 depends from it.

Claim Rejections - 35 USC § 102

Claims 1, 8, 10, 23, 30, 39-44 are rejected under 35 U.S.C. 102 (e) as being anticipated by Khwaja et al.

Khwaja teaches the use of St. John's Wort (*Hypericum perforatum*) extract to treat the claimed disease, see abstract, cols. 10, 20, 23-24, 27-28, etc. Khwaja teaches that diseases/conditions such as arrhythmia (col. 23, line 44-col. 24, line 18) can be treated with the extract.

Applicant argues that Khwaja teaches a number of assays that can be used for testing for substances for consistent quality and suitability as a therapeutic agent, but it is clear on col. 27, lines 35-end through col. 28, line 35 that these materials taught by

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the patent are useful for the above mentioned disease states which are claimed by applicant. All Khwaja has to do is teach that it is desirable to do so under 35 USC 102. Further it is noted on col. 20, lines 13-20, that ethanol and/or methanol can be used to extract the plants, i.e. Saint John's Wort.

Claim Rejections - 35 USC § 103

Claims 1, 8, 10, 23, 30, 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja et al.

The above discussion is applied here. The arguments are the same as above. Thus, the rebuttal is the same as above.

The amount of Saint John's Wort used in the claimed method is simply the choice of the artisan in an effort to optimize the desired results. Through routine experimentation one could have arrived at the claimed effective amount since the range of the effective amount is so broad to begin with. Further it is noted on col. 20, lines 13-20, that ethanol and/or methanol can be used to extract the plants, i.e. Saint John's Wort.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
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MVM